REMARKS

I. Status of Claims

Claims 1-62 and 64-83 are currently pending. No claims have been amended by this response.

II. Information Disclosure Statement

Applicants note that the Examiner did not indicate that WO 99/36047 had been considered on the Form PTO/SB/08 filed April 22, 2005.

Applicants respectfully request the Examiner's consideration of the reference and the indication of such consideration by initialing the Form PTO/SB/08. A copy of the Form PTO/SB/08 has been attached to this response for the Examiner's convenience.

III. Rejections Under 35 U.S.C. § 103(a)

A. Restle in view of Ziegler, Margosiak, and Knowlton

The Examiner has maintained the rejection of claims 1-19, 21-23, 28-62, and 68-83 under 35 U.S.C. § 103(a) as obvious over EP 0842652 A1 to Restle et al. ("Restle") in view of U.S. Patent No. 5,135,748 to Ziegler et al. ("Ziegler"), U.S. Patent No. 6,533,873 to Margosiak et al. ("Margosiak"), and "POUCHER'S PERFUMES, COSMETICS, AND SOAPS: EMULSION THEORY" by Knowlton et al. ("Knowlton") as set forth in the Office Action of December 23, 2004. Final Office Action at page 2. Applicants respectfully disagree and traverse this rejection for at least the following reasons in addition to the reasons of record.

The Examiner has acknowledged that Restle does not teach the cationic polymers of claims 5-16 and relies on Ziegler for the addition of cationic polymers.

Office Action of December 23, 2004, at page 4. The Examiner alleges that the cationic polymers would stabilize the composition. *Id.*

Ziegler, however, does not disclose that the cationic polymers could stabilize nanoemulsions. Furthermore, there is no teaching in the references that would suggest to one skilled in the art that the introduction of those polymers would not modify the particle size of the nanoemulsion. Thus, there is no motivation to add the cationic polymers of Ziegler to the nanoemulsion of Restle.

Additionally, the Examiner acknowledges that Restle and Ziegler fail to teach that the nanoemulsion having the claimed turbidity. *Id.* The Examiner, however, asserts that it would have been obvious to one of ordinary skill in the art that the nanoemulsion of Restle, which has an average particle size of oil globules smaller than 150 nm, would be translucent to transparent and have a turbidity at or below 150 NTU based on the respective teachings of Knowlton and Margosiak. *Id.* at page 5.

In the Final Office Action of July 13, 2005, the Examiner states that "applicants are respectfully reminded that the pending rejection is not based on inherency theory." Final Office Action at page 3. Absent inherency, it is not clear how the Examiner is applying the prior art, considering the Examiner is asserting that certain properties not expressly recited in the primary reference are present. To support this pseudo-inherency position, the Examiner relies on secondary references, which allegedly teach particle sizes and turbidity properties within the claimed ranges.

The Examiner cannot shirk the burden to establish a *prima facie* case of obviousness by making an inherency-based rejection without meeting the requirements set forth by U.S. case law and the M.P.E.P. The use of the word "obvious" is not sufficient to avoid the burden of making a *prima facie* case inherency rejection.

In the Office Action of December 23, 2004, the Examiner made the following rejection:

It would have been obvious to one of ordinary skill in the art that the Restle nanoemulsion whose average particle size of oil globules is smaller than 150 nm is translucent to transparent, as suggested by Knowlton, and has turbidity at or below 150 NTU, as suggested by Margosiak et al.

Office Action of December 23, 2004, at page 5 (emphasis added).

As is clearly seen by the underlined portions above, the Examiner has <u>not</u> made an obviousness rejection based on Knowlton and Margosiak as the Examiner purports. The Examiner has not identified any differences between the prior art and the present claims. Nor has the Examiner modified the prior art in any way. The Examiner is not alleging that it would have been obvious to modify the composition of Restle to have a turbidity ranging from 60 NTU to 600 NTU. Instead, the Examiner is saying that the nanoemulsion of Restle <u>has</u> the claimed properties based on the alleged evidence provided by Knowlton and Margosiak. Thus, the Examiner's rejection is an inherency rejection.

Regardless of whether the rejection is relying on the Knowlton and Margosiak references to support an obvious modification or to evidence inherency, the Examiner has failed to meet the required burden to establish a *prima facie* case of obviousness or inherency.

To make a valid obviousness rejection, "patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in <u>each and every case</u>." M.P.E.P. § 2141 (emphasis in original). The Examiner has not followed this standard of patentability as set forth in *Graham v. Deere*. The Examiner has merely stated that the composition of Restle has the claimed turbidity based on generalizations disclosed in Knowlton and Margosiak that have no teaching or suggestion to modify the composition of Restle.

One of the requirements to establish a *prima facie* case of obviousness is that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. M.P.E.P. § 2143.01.

As the Examiner acknowledged, Restle does not teach or suggest a nanoemulsion having a turbidity ranging from 60 NTU to 600 NTU. The Examiner alleges that the composition of Restle would have the claimed turbidity because Knowlton generically discloses that size may be a factor in the appearance of a composition and Margosiak discloses that a specific composition has a certain appearance and a turbidity less than 105 NTU.

Knowlton and Margosiak fail to cure the deficiencies of Restle because neither Knowlton nor Margosiak teach or suggest modifying the composition of Restle to have the claimed elements. Knowlton does not teach or suggest that the composition of Restle should have a certain appearance. Nor does Margosiak suggest that the composition should have a turbidity ranging from 60 NTU to 600 NTU simply because

the composition happens to have an appearance that Knowlton suggests may possibly have the same particle size as the composition of Restle. In fact, the Examiner's position is undercut by the express teachings of Knowlton, which discloses that "it is foolish to generalize on the correlation of emulsion appearance with the size of the dispersed phase particles." A *prima facie* case of obviousness cannot be established on such a string of generalities without any motivation to combine the references in a manner that results in the claimed invention. Without some teaching, suggestion, or motivation to modify the composition of Restle, an obviousness rejection is improper because there is no *prima facie* case of obviousness.

The rejection also fails under an inherency theory because the references clearly demonstrate that the claimed properties are not necessarily present. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (emphasis added). The Office has failed to meet this burden.

Despite the assertions regarding the teachings of Knowlton and Margosiak, neither of these references provides the necessary teachings to support an inherency rejection. In fact, instead of providing extrinsic evidence that makes clear that the

"missing subject matter is necessarily present in the thing described in the reference,"

Knowlton clearly teaches why the missing subject matter is merely a possibility.

The Examiner relies upon Knowlton as teaching that "when particle size falls below 0.1 microns (100 nm) the emulsions appear blue-gray to translucent, to transparent." Office Action of December 23, 2005, at page 4. Knowlton, however, also clearly states that "it is <u>foolish</u> to generalize on the correlation of emulsion appearance with the size of the dispersed phase particles." Knowlton at page 552 (emphasis added). Therefore, Knowlton cannot support a rejection based on inherency because Knowlton clearly teaches that the claimed property is a mere possibility. Such a teaching is far from the requisite evidence necessary to show that the missing subject matter is necessarily present.

Margosiak similarly fails to provide the extrinsic evidence necessary to show that the nanoemulsion of Restle would have the claimed turbidity. Margosiak teaches that a smaller turbidity is desired and that the turbidity must be less than 105 NTU. Margosiak at col. 10, lines 20-29. This teaching includes turbidities below the lower claimed limit of 60 NTU. Thus, the turbidity of the composition of Margosiak does not necessarily fall within the claimed range of 60 NTU to 600 NTU because the composition of Margosiak may have a turbidity smaller than 60 NTU.

Therefore, based on the uncertainty between particle size and appearance,
Knowlton is incapable of providing clear evidence that the emulsion of Restle
necessarily has a translucent appearance based on the size of the particles.
Furthermore, Margosiak cannot cure the deficiencies of Knowlton because Margosiak
does not disclose the size of the particles in the composition. Additionally, based on the

teachings of the prior art, the combination of Knowlton and Margosiak cannot support a rejection based on obviousness because the prior art clearly shows that turbidity cannot be determined from particle size alone.

The Examiner's statements made in the Final Office Action also fail to overcome the reference's deficiencies. The Examiner states that "the intent of the author of the Knowlton reference was to suggest, and one of ordinary skill in the art would have interpreted the teaching as a whole as, that the particle size of dispersed phase is a significant factor in determining the appearance of an emulsion." Final Office Action at page 3. The Examiner also states that Applicants admit in the specification that the transparency of the composition is due to the small particle size of the oil droplets. Final Office Action at page 4.

While Applicants are not suggesting that particle size does not affect the appearance of an emulsion, the Examiner is not addressing the recited claim elements. Applicants are not claiming the appearance of the nanoemulsion. The claims recite the turbidity of the nanoemulsion. Turbidity and appearance are not the same.

Furthermore, the Examiner's own statements undermine the assertions that the nanoemulsion of Restle has the claimed turbidity. As the Examiner acknowledges, size is only a <u>factor</u> in determining turbidity. Thus, the turbidity of a composition does not depend only on the particle size. For example, turbidity calibration standards use particles that are uniform in size, and yet they can provide a turbidity ranging from 0.10 NTU to 10,000 NTU by changing the concentration. See Turbidity Calibration Standards Evaluated from a Different Perspective, at http://www.apsstd.com/news/turbidityPerspective.php (attached to Reply filed April 21,

2005). Clearly, size is not the only factor, and any conclusions regarding turbidity based solely on size are erroneous and immediately suspect. As Knowlton discloses, "it is foolish to generalize on the correlation of emulsion appearance with the size of the dispersed phase particles."

For at least the foregoing reasons, the combined teachings of Restle, Zeigler, Knowlton, and Margosiak do not render obvious independent claims 1, 68-73, 75, 77, and 78, and the claims dependent thereon. Thus, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103.

B. Restle in view of Ziegler, Margosiak, and Knowlton, and further in view of Simonnet

The Examiner has maintained the rejection of claims 24-27 under 35 U.S.C. § 103(a) as obvious over Restle, Ziegler, Margosiak, and Knowlton, and further in view of EP 078114 A1 to Simonnet ("Simonnet") as set forth in the Office Action of December 23, 2004. Final Office Action at page 2. Applicants respectfully disagree and traverse this rejection for at least the following reasons in addition to the reasons of record.

The Examiner acknowledges that Restle, Ziegler, Margosiak, and Knowlton fail to teach the amphiphilic anionic lipids claimed by the Applicants. See Office Action of December 23, 2004, at page 5. The Examiner therefore relies on Simonnet to teach the amphiphilic anionic lipids and alleges that it would have been obvious to one skilled in the art to modify the composition of the combined references because of the expectation of successfully producing a transparent cosmetic emulsion compsition with well known surfactants in the art. *Id.* at pages 5-6

As and initial matter, Simonnet does not remedy the deficiencies of the combined disclosures of Restle, Ziegler, Knowlton and Margosiak with respect to claims 24-27. Simonnet neither teaches nor suggests a nanoemulsion having a turbidity ranging from 60 NTU to 600 NTU as recited in the present independent claims. To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. None of the references, either alone or in combination, teach or suggest the elements recited in the present claims. Therefore, the Examiner has not met this burden because the references do not teach all of the limitations recited in the claims.

Furthermore, the fact that a surfactant is well-known does not make it obvious to use it in the composition of Restle and certainly to achieve the claimed composition. As explained above, there must be some teaching or suggestion to modify the composition within the prior art. See M.P.E.P. § 2143.01. Thus, without a teaching or suggestion in the prior art, a *prima facie* case of obviousness has not been established.

Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejection.

C. Restle in view of Ziegler Margosiak, Knowlton, and Simonnet, and further in view of Matzik

The Examiner has maintained the rejection of claim 20 under 35 U.S.C. § 103(a) as obvious over Restle, Ziegler, Margosiak, Knowlton, and Simonnet, and further in view of U.S. Patent No. 5,716,418 to Matzik et al. ("Matzik") as set forth in the Office Action of December 23, 2004. Final Office Action at page 2. Applicants respectfully

disagree and traverse this rejection for at least the following reasons in addition to the reasons of record.

The Examiner acknowledges that Restle, Ziegler, Margosiak, Knowlton, and Simonnet fail to teach the anionic amphiphilic lipids claimed by the Applicants. *See* Office Action of December 23, 2004, at page 5. The Examiner therefore relies on Matzik to teach the amphiphilic anionic lipids and asserts that it would have been obvious to modify the composition of the combined references by adding the anionic amphiphilic lipid as taught by Matzik because of the "expectation of successfully producing cosmetic composition with a known surfactant in the art. Office Action of December 23, 2004, at page 6.

Matzik, however, does not remedy the deficiencies of the combined disclosures of Restle, Ziegler, Knowlton, Margosiak, and Simonnet with respect to claims 24-27. Matzik neither teaches nor suggests a nanoemulsion having a turbidity ranging from 60 NTU to 600 NTU as recited in the present independent claims. To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. None of the references, either alone or in combination, teach or suggest the elements recited in the present claims. Therefore, the Examiner has not met this burden because the references do not teach all of the limitations recited in the claims.

Furthermore, the fact that a surfactant is known does not make it obvious to use it in the composition of Restle, and certainly not to achieve the claimed composition.

Nor would one skilled in the art be motivated to use that surfactant in a specific

composition without some motivation to use that surfactant. Thus, without a teaching or suggestion in the prior art, a *prima facie* case of obviousness has not been established.

Accordingly, Applicants respectfully request that the reconsideration and withdrawal of this rejection.

D. Restle in view of Ziegler, Margosiak, Knowlton, Simonnet, and Matzik, and further in view of Decoster

The Examiner has maintained the rejection of claims 64-67 under 35 U.S.C. § 103(a) as obvious over Restle, Ziegler, Margosiak, Knowlton, Simonnet, and Matzik, and further in view of JP H10-338899 to Decoster et al. ("Decoster") as set forth in the Office Action of December 23, 2004. Final Office Action at pages 2-3. Applicants respectfully disagree and traverse this rejection for at least the following reasons in addition to the reasons of record.

The Examiner acknowledges that the combination of Restle, Ziegler, Margosiak, Knowlton, Simonnet, and Matzik fails to teach the use of aminosilicone, as recited in the present claims. The Examiner alleges that it would have been obvious to one skilled in the art to combine the teachings of Decoster with the combination of Restle, Ziegler, Margosiak, Knowlton, Simonnet, and Matzik because Restle teaches the applicability of emulsions in shampoo or skin cleansing formulations, Decoster teaches the applicability of the conditioning system in detergent compositions, and both references teach using quaternary ammonium cationic polymers. See Office Action of December 23, 2004, at page 7-8. Applicants respectfully disagree with the Examiner's assertions and traverse the rejection for at least the following reasons.

To establish a *prima facie* case of obviousness, there must be motivation to combine the reference teachings, there must be a reasonable expectation of success, and the combination of references must teach all of the claim limitations. The Office has not met this burden for at least the foregoing reasons. Decoster does not remedy the deficiencies of the primary reference. Indeed, the Examiner merely cites this reference for its alleged teachings related to aminosilicone, including the benefits associated with its use. Therefore, Applicants disagree with the Examiner's position for the additional reason that there is no motivation for one skilled in the art to combine the references in the manner presented, and one skilled in the art would not expect the composition resulting from the combination of Restle, Ziegler, Knowlton, Margosiak, Simonnet, Matzik, and Decoster to have the alleged benefits.

Central to the Examiner's rejection is the alleged conditioning benefit of Decoster. As disclosed by Decoster, however, this benefit, can only be achieved "in a case where (A): A specified detergent base and (B): A conditioning system inclusive of at least one cationic polymer and at least one aminosilicone are used together." See Decoster at 12. The specified detergent base of Decoster requires "at least one sulfuric acid alkyl ether-type anionic surfactant and at least one C₈ ~ C₂₀ alkylbetaine-type amphoteric surfactant." Decoster at 12. In contrast, Restle requires, *inter alia*, an oil-inwater emulsion whose oil globules have an average size that is smaller than 150 nm and that includes an amphiphilic lipid phase having nonionic lipids and cationic lipids. See Restle at 2. One skilled in the art would not have been motivated to combine the aminosilicone of Decoster with the combined composition of Restle, Ziegler, Knowlton, Margosiak, Simonnet, and Matzik because Decoster clearly requires a specified base

detergent in combination with the conditioning system to achieve a conditioning benefits. Because the specified base detergent is neither required nor disclosed by Restle, Ziegler, Knowlton, Margosiak, Simonnet, or Matzik, this combination of references is therefore improper.

In the Final Office Action, the Examiner attempts to rebut Applicants prior argument by asserting that "[e]ven if the conditioning benefits of the Decoster composition were obtained only in the detergent base as described in that reference, the claimed invention in instant claims 64-68 does not exclude the presence of the detergent base in the claimed composition." Final Office Action at page 5.

The Examiner is reminded that there must be some teaching or motivation in the prior art to establish a *prima facie* case of obviousness. Furthermore, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01; *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Moreover, obviousness requires a reasonable expectation of success. M.P.E.P. § 2143.02.

The Examiner has failed to establish a *prima facie* case of obviousness for the suggested combination of references. While the present claims are open to additional components, the Examiner has provided no suggestion or teaching why one skilled in the art would add all of the necessary components of Decoster to the composition of Restle simply for an alleged improvement in conditioning. Both Restle and Decoster teach fully functional and useful compositions on their own. The Examiner has failed to provide any motivation for adding the detergent of Decoster, which is a necessary component to achieve the alleged benefits, to the composition of Restle. Without

Attorney Docket No. 05725.0830-00 Application No. 09/765,675

proper motivation, one skilled in the art would not combine the necessary components

of Decoster to the composition of Restle. Since the compositions of Decoster and

Restle have different functions, one skilled in the art would not have a reasonable

expectation of success in the combination because there is no evidence suggesting that

the one or both of the functions would not be destroyed by the combination.

Accordingly, Applicants respectfully request the reconsideration and withdrawal

of the rejection.

IV. Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration

of this application and the timely allowance of pending claims 1-62 and 64-83.

Please grant any extensions of time required to enter this response and charge

any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,

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/Louis Troilo/

Dated: November 14, 2005

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Attachment:

Copy of Form PTO/SB/08 filed April 22, 2005.

15